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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------------------------------|----------------------|---------------------|------------------|
| 10/714,586 | 11/14/2003 | Timothy J. Patrick | 101360-63 | 1671 |
| | 7590 08/13/200 CLENNEN & FISH LL | EXAMINER | | |
| WORLD TRADE CENTER WEST | | | LACYK, JOHN P | |
| BOSTON, MA | BOULEVARD 02210-2604 | | ART UNIT | . PAPER NUMBER |
| , | | | 3735 | • |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 08/13/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|--|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| Office Action Summany | 10/714,586 | PATRICK ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | John P. Lacyk | 3735 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status · | | | | | | |
| 1) Responsive to communication(s) filed on 28 F | ebruary 2007. | | | | | |
| | s action is non-final. | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-3 and 6-33</u> is/are pending in the ap | 4) Claim(s) 1-3 and 6-33 is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-3,6-29 and 31-33</u> is/are rejected. |)⊠ Claim(s) <u>1-3,6-29 and 31-33</u> is/are rejected. | | | | | |
| 7)⊠ Claim(s) 30 is/are objected to. | Claim(s) <u>30</u> is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | | | | | |
| Application Papers | • | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the E | xaminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
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| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Paper No(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal F 6) Other: | | | | | |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-3, 6-29, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (5,429,582) in view of Tam et al (6,458,069). Williams discloses a brachytherapy device for treating tissue surrounding a resected cavity having a catheter body member having proximal and distal portions and an expandable member that defines a spatial volume. The volume is configured to receive a radiation source that would inherently provide a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member. The embodiment as shown in Figure 7 further includes a treatment agent that is delivered to adjacent. tissue when the device is positioned within the tissue cavity. Williams discloses the claimed device and method except for the treatment agent being releasably mated with the expandable surface member. Tam et al discloses a similar device that provides radiation therapy to a site in a body lumen having a catheter body member having proximal and distal portions and an expandable member that defines a spatial volume. Tam et al also teaches that a treatment agent is releasably mated with the expandable member, by coating or disposing the treatment agent on all or a portion of the outer surface and the inner surface of the expandable member (column 17, lines 56-67). Therefore a modification of Williams such that the treatment agent is coated onto the expandable member to deliver the treatment agent would have been obvious to one

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skilled in the art in view of Tam et al since this would have been the mere substitution of one well known way to deliver a treatment agent and radiation source for another. Tam et al further teaches mixing the treatment agent with a binding agent (column 7, lines 1-5); using more than one treatment agent including radioactive and nonradioactive agents; having different agents disposed in different layers (Figures 4-7 and 9-9A); disposing the radiation source outside the expandable member or within the expandable surface member (column 22, lines 51-59). While embodiments of Williams is directed to cavities created by removing brain tumors, Williams also states that tumors in other sites is also included (column 1, line 64- column 2, line 2); also Tam et al teaches that the device while shown being used in a body lumen is well known to use any other location accessible by catheter which may benefit from radiation delivery including surgically created pathways, esophagus, urethra, ureters, etc. Therefore in view of the teachings to use the device as claimed in claims 27, 31-33 would have been obvious to one skilled in the art since these are well known places within the body to use radiation sources for therapy.

- 3. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 4. Applicant's arguments with respect to claims 1-3, 6-33 have been considered but are most in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Primary Examiner
Art Unit 3735

J.P. Lacyk